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08/507,863 07/27/95 GREFF

R 018413-002

EXAMINER

NILAND, P

15M1/0213

ART UNIT

PAPER NUMBER

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#5

1511

DATE MAILED: 02/13/96

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined  Responsive to communication filed on \_\_\_\_\_  This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. Notice of References Cited by Examiner, PTO-892.  
2.  Notice of Draftsman's Patent Drawing Review, PTO-948.  
3.  Notice of Art Cited by Applicant, PTO-1449.  
4.  Notice of Informal Patent Application, PTO-152.  
5.  Information on How to Effect Drawing Changes, PTO-1474.  
6.  \_\_\_\_\_

**Part II SUMMARY OF ACTION**

1. Claims 1-15 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2.  Claims \_\_\_\_\_ have been cancelled.

3.  Claims \_\_\_\_\_ are allowed.

4. Claims 1-15 are rejected.

5.  Claims \_\_\_\_\_ are objected to.

6.  Claims \_\_\_\_\_ are subject to restriction or election requirement.

7.  This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8.  Formal drawings are required in response to this Office action.

9.  The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are  acceptable;  not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10.  The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been  approved by the examiner;  disapproved by the examiner (see explanation).

11.  The proposed drawing correction, filed \_\_\_\_\_, has been  approved;  disapproved (see explanation).

12.  Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has  been received  not been received  been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.

13.  Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14.  Other

**EXAMINER'S ACTION**

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15. The preamendment of 12/4/95 has been entered. Claims 1-15 are pending.

16. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

17. Claims 1-15 are rejected under 35 U.S.C. § 103 as being unpatentable over US Pat. No. 5443454 Tanabe et al. in view of Taki, "Possibility and Limit of Intravascular Surgery", Medical Tribune, October 26, 1989, Pages 46-47, US Pat. No. 4795741 Leshchiner et al., US Pat. No. 5202352 Okada et al., and US Pat. No. 4079124 Winchell.

Tanabe et al. and Taki disclose the use of a composition of 5% ethylene vinyl alcohol copolymer and 100.ml of DMSO which falls within the scope of the instantly claimed ingredients (a) and (c) of the instant claims 1-3 and 7-9. The ethylene vinyl alcohol copolymer is 33 mole % ethylene and therefore 67 mole % vinyl alcohol, which falls within the scope of the instant claims 2 and 8.

See column 2, lines 7-13 and 42-51; column 11, lines 13-49; and column 12, lines 13-50 of Tanabe et al.. Tanabe et al. discloses adding X-ray contrast medium to the embolic material but is silent as to the identities of the contrasting materials. See column 11, lines 50-53. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use tantalum, tantalum oxide, or barium sulfate as the X-ray contrast agent of Tanabe et al. , in the instantly claimed amounts, because Leshchiner et al. discloses the use of powdered tantalum and barium sulfate in embolizing compositions as X-ray contrast agents at column 3, lines 36-47, in amounts falling within the amounts of the instant claims, Winchell discloses tantalum oxide as an X-ray contrasting agent which is biocompatible at column 3, lines 1-35 and column 6, lines 41-58, Okada et al. recognizes the surfactant ability of polyvinyl alcohol compounds at column 9, lines 7-9, the surfactant ability of the polyvinyl alcohol copolymer and the viscosity of the solution of copolymer of Tanabe et al. are expected to maintain the X-ray contrasting agents of Leschiner et al. in a dispersed state just as pigment is typically dispersed in solvent based paints or spinning solutions of polymer, and the X-ray contrast agents of Leshchiner et al. are expected to provide the surgeon the ability to see the embolized area with X-rays, as specified by Tanabe et al.. The applicant provides no unexpected results which are commensurate in scope with

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the cited prior art and the instantly encompassed ingredient amounts, polymer molecular weights, vinyl alcohol to ethylene ratios, contrasting agent particle sizes, and other physical characteristics encompassed by the instant claims and the cited prior art which materially affect the instantly claimed composition's properties.

The embolizing method steps described by Tanabe et al. fall within the scope of the method steps of the instant claims 7-12. The patentee is silent as to the injection rates of the instant claims 13-15. Tanabe et al. does disclose the formation of filaments, which falls within the scope of the instant claim 15. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to inject the embolizing solution discussed above by the method according to Tanabe et al. at the injection rates of the instant claims 13-15 because the choice of such injection rates is within the ability of the ordinary skilled artisan, i.e. the surgeon, as evidenced by the patentee's silence as to the choice of injection rates, the injection rate influences whether or not the spinning orifice clogs up, defining a minimum injection rate usable, and whether or not the blood vessel bursts in extreme cases and more routinely whether or not the extruded filaments shoot past the site at which they are desired to embolize. The applicant has demonstrated no unexpected results for

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the injection rates of the instant claims 13-15 in a manner which is commensurate in scope with the cited prior art and the instant claims.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Niland on Monday to Friday from 9:30 to 6:00 whose telephone number is (703) 308-3510. If the examiner cannot be reached and the inquiry is urgent, call Paul Michl at (703) 308-2451. Direct any faxes to members of Art Unit 1511 to (703) 305-5433.

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February 7, 1996



Patrick Niland  
Patent Examiner  
Art Unit 1511